



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: U.S. COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10 081,051 | 02 20 2002 | Anthony F. Barbet | UF-299XC1 | 1773 |

23557 7590 09 29 2003

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
2421 N.W. 41ST STREET
SUITE A-1
GAINESVILLE, FL 326066669

| |
|--------------------|
| EXAMINER |
| BASKAR, PADMAVATHI |

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1645 | 10 |

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

| | | |
|------------------------------|---------------------|---------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/081,051 | BARBET ET AL. |
| | Examiner | Art Unit |
| | Padmavathi v Baskar | 1645 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) ____ is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . | 6) <input type="checkbox"/> Other: ____ . |

Election/Restrictions

1. Restriction to one of the following groups of invention is required under 35 U.S.C. 121:

I. Claims 1-7 and 16 drawn to an isolated polynucleotide, host cell classified in class 536, subclass 23.7. Further restriction to one SEQ.ID.NO required (see paragraph # 4).

II. Claims 8-10 drawn to an isolated polypeptide classified in class 530, subclass 350. Further restriction to one SEQ.ID.NO required (see paragraph # 4).

III. Claim 11-15 drawn to a method of inducing in an individual immunity in an individual comprising administration of a composition comprising polypeptide or polynucleotide classified in class 424, subclass 184.1 and 130.1 Further restriction to one SEQ.ID.NO required (see paragraph # 4).

IV. Claim 17 drawn to a method of detecting the presence of *Ehrlichia ruminantium* using polypeptide or a polynucleotide classified in class 435, subclass 7.22. Further restriction to one SEQ.ID.NO required (see paragraph # 4).

2. The inventions are distinct, each from the other because of the following reasons:

Group I is directed to DNA which consists of nucleic acids, Groups II is directed to polypeptides, which are made of amino acids. These products are different to each other structurally, biochemically and functionally and are drawn to patentably distinct inventions which have materially different physical and chemical properties and structures as represented by their divergent sequences.

3. Groups III and IV are different methods utilizing different products namely DNA, or protein. Thus, Inventions IV and V are patentably different methods using patentably distinct and different biological reagents, different method steps that result in different outcome.

Art Unit: 1645

Distinct Inventions

4. For each group of inventions I-IV above, restriction to one of the following SEQ.ID.NO is also required under 35 USC 121. Therefore, election is required of one of inventions I – IV and one SEQ ID NO.

Inventions SEQ ID NO: 2,3, 4,8,10,12,15, 17, 19, 20, 21, 23, 24, 25, 27, 29, 31, 32, 33, 34, 36, 38, 39, 41, 43, 45, 46, 47, 48, 51, 52, 53, 54, 56, 57, 58, 59, 61, 63, 64, 65, 67, 68, 69, 70, 72, 73, 74, 75, 77, 78, 79, 81, 82, 84, 85, 87, 88, 89, 90, 92, 93, 94, 95, 96, 98, 100, 101, 103, 104, 105, 106, 108, 110, 114, 115 and

Inventions SEQ.ID.NO: 5, 9, 11, 16, 18, 22, 26, 28, 30, 35, 37, 40, 42, 44, 55, 60, 62, 66, 71, 76, 80, 83, 86, 89, 97, 99, 102, 107, 109, 111, 112, 113, and 116 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects. Thus, each sequence is unique and patentably distinct since each sequence has a different structure with specific amino acid or nucleic acid and is identified by a specific SEQ.ID.NO.

Restriction is deemed proper because these products appear to constitute patentably distinct inventions. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such sequence is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed SEQ.ID.NO from any group elected.

Art Unit: 1645

5. Invention I is related to inventions III and IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Group I can be used to prepare hybrid clones of Ehrlichia ruminantium strains and need not be used in the inventions III and IV.

6. Invention II is related to inventions III and IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Group II can be used in immunoaffinity chromatography methods for purifying antibodies and need not be used in the inventions III and IV.

7. Because these inventions are distinct for the reason given above, have acquired a separate status in the art as shown by their different classification, and while searches may overlap they are not coextensive, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1645

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 A.M. to 4:00 P.M. EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

9/25/03

hp

SUPER
TP

WER